UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

26161 7590 01/04/2010

FISH & RICHARDSON PC
P.O. BOX 1022
MINNEAPOLIS, MN 55440-1022

EXAMINER	
OLSON, ERIC	
ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 01/04/2010

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/767,019	01/29/2004	George E. Wright	07917-183001 / UMMC 03-23	4717

TITLE OF INVENTION: NOVEL ANTIHERPES DRUG COMBINATIONS

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	$755	$300	$0	$1055	04/05/2010

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PTOL-85 (Rev. 08/07) Approved for use through 08/31/2010.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

26161 7590 01/04/2010

FISH & RICHARDSON PC
P.O. BOX 1022
MINNEAPOLIS, MN 55440-1022

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/767,019	01/29/2004	George E. Wright	07917-183001 / UMMC 03-23	4717

TITLE OF INVENTION: NOVEL ANTIHERPES DRUG COMBINATIONS

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	$755	$300	$0	$1055	04/05/2010

EXAMINER	ART UNIT	CLASS-SUBCLASS
OLSON, ERIC	1623	514-263370

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

❑ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

❑ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) the names of up to 3 registered patent attorneys or agents OR, alternatively,

(2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 _____

2 _____

3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ❑ Individual ❑ Corporation or other private group entity ❑ Government

4a. The following fee(s) are submitted:

❑ Issue Fee

❑ Publication Fee (No small entity discount permitted)

❑ Advance Order - # of Copies _____

4b. Payment of Fee(s): **(Please first reapply any previously paid issue fee shown above)**

❑ A check is enclosed.

❑ Payment by credit card. Form PTO-2038 is attached.

❑ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)

❑ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27.

❑ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/767,019	01/29/2004	George E. Wright	07917-183001 / UMMC 03-23	4717

26161 7590 01/04/2010

FISH & RICHARDSON PC
P.O. BOX 1022
MINNEAPOLIS, MN 55440-1022

EXAMINER	
OLSON, ERIC	
ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 01/04/2010

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 409 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 409 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

PTOL-85 (Rev. 08/07) Approved for use through 08/31/2010.

Notice of Allowability	Application No.	Applicant(s)	
	10/767,019	WRIGHT, GEORGE E.	
	Examiner	Art Unit	
	ERIC S. OLSON	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *Applicant's amendment and arguments submitted October 6, 2009*.

2. ☒ The allowed claim(s) is/are *1, 10-19, 32, and 36-46* .

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

/Eric S Olson/ Examiner, Art Unit 1623	/Shaojia Anna Jiang/ Supervisory Patent Examiner, Art Unit 1623

Examiner's Amendment

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Janice DeYoung on December 14, 2009.

The claims are amended as follows:

1. (Currently Amended) A composition comprising a combination of:

a) 2-phenylamino-9-(4-hvdroxybutyl)-6-oxopurine, or an ester or salt thereof, and

b) an antiherpes substance selected from the group consisting of acyclovir ~~monophosphate~~, ganciclovir ~~monophosphate~~, cidofovir, and foscarnet, or any combination thereof, or an ester or salt thereof.

12. (Cancelled)

13. (Cancelled)

32. (Currently Amended) A kit for treatment of a Herpes simplex virus infection in a mammal, the kit comprising:

a) 2-phenylamino-9-(4-hvdroxybutyl)-6-oxopurine, or an ester or salt thereof,

b) an antiherpes substance selected from the group consisting of acyclovir ~~monophosphate~~, ganciclovir ~~monophosphate~~, cidofovir, and foscarnet, or any combination thereof, or an ester or salt thereof, and

c) instructions for administering (a) and (b) concurrently or within a sufficiently close time to achieve coexistent concentrations Of (a) and (b) in subject.

38. (Cancelled)

Detailed Action

This office action is a response to applicant's communication submitted October 6, 2009 wherein claims 1, 11-13, 32, 37-40, and 43-46 are amended and claims 2, 3, 5, 7, 8, 33, 34, and 47-50 are cancelled. This application claims benefit of provisional application 60/443519, filed January 29, 2003.

Claims 1, 10-19, 32, and 36-46 are pending in this application.

Claims 1, 11-13, 32, 37-40, and 43-46 are directed to an allowable product. Pursuant to the procedures set forth in MPEP § 821.04(B), claims 41 and 42, directed to the process of making or using an allowable product, previously withdrawn from consideration as a result of a restriction requirement, are hereby rejoined and fully examined for patentability under 37 CFR 1.104.

Because all claims previously withdrawn from consideration under 37 CFR 1.142 have been rejoined, **the restriction requirement as set forth in the Office action mailed on January 10, 2007 is hereby withdrawn**. In view of the withdrawal of the restriction requirement as to the rejoined inventions, applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Reasons for Allowance

Applicant's amendment and arguments, submitted October 6, 2009, with respect to the rejection of instant claims 1-3, 7, 8, 10, 14, 16-18, 32-34, 36, 43, 45, and 50 under 35 USC 103(a) for being obvious over Wright et al. in view of Gilbert et el., has been fully considered and found to be persuasive to remove the rejection as Applicant has shown an unexpected synergistic interaction between the two components of the composition as discussed below. Therefore the rejection is withdrawn.

Applicant's amendment and arguments, submitted October 6, 2009, and the enclosed examiner's amendment, have been fully considered with respect to the rejection of instant claims 1-3, 5, 7, 8, 11-14, 15-18, 32-34, 37-40, and 43-50 under 35 USC 103(a) for being obvious over Wright et al. in view of Gilbert et el., and found to be persuasive to remove the rejection as the claims have been amended to no longer encompass compositions comprising acyclovir or ganciclovir monophosphate. Therefore the rejection is withdrawn.

Applicant's amendment, submitted October 6, 2009, with respect to the rejection of instant claims 1-3, 5, 7, 8, 10-19, 32-34, and 36-40 under 35 USC 112, second paragraph, for indefinitely reciting analogs of nucleosides, has been fully considered and found to be persuasive to remove the rejection as the indefinite language has been removed from the claims. Therefore the rejection is withdrawn.

Applicant's amendment, submitted October 6, 2009, with respect to the rejection of instant claims 1, 2, 7, 8, 14-19, 32, 34, 39, 40, and 50 under 35 USC 112, first paragraph, for lacking enablement for compositions comprising the full scope of pre-phosphorylated or phosphonate nucleoside analogs, pyrophosphate analogs, and nucleoside analogs, has been fully considered and found to be persuasive to remove the rejection as the claims have been amended to only recite certain specific drugs that are enabled by Applicant's disclosure. Therefore the rejection is withdrawn.

Applicant's amendment and arguments, submitted October 6, 2009, and the enclosed examiner's amendment, have been fully considered with respect to the rejection of instant claims 1-3, 7, 8, 10, 14, 16-18, 32-34, 36, 43, 45, and 50 under 35 USC 103(a) for being obvious over Wright et al. in view of Naesens et el., and found to be persuasive to remove the rejection as Applicant has shown an unexpected synergistic interaction between the two components of the composition as discussed below. Therefore the rejection is withdrawn.

Currently claims 1, 10-19, 32, and 36-46 are pending in this application and have been examined on the merits herein. Applicant's amendment submitted October 6, 2009, is seen to be persuasive to remove all rejections of record in the previous office action and place the application in condition for allowance. Reasons for allowance are as follows:

The claims are adequately described and enabled by the specification as originally filed. For example. pp. 2-4 of the specification describe combinations of antiherpes drugs comprising HPBG and additionally comprising another component such as acyclovir, gancyclovir, cidofovir, or foscarnet. As all of these therapeutic agents are already known individually in the prior art, for example Wright et al., Gilbert et al., or Naesens et al. (References of record in previous action) making these compositions would not pose any difficulty to one skilled in the art. Finally, pp. 13-16 disclose working examples for the inhibition of HSV infection using the claimed combinations, enabling one skilled in the art to use the claimed invention. Therefore the claims meet the requirements of 35 USC 112.

Furthermore the claimed invention is seen to be novel and non-obvious over the prior art. The prior art does not disclose any compositions comprising both 2-phenylamino-9-(4-hvdroxybutyl)-6-oxopurine and one of the additional therapeutic agents acyclovir, ganciclovir, cidofovir, or foscarnet. Although the prior art does disclose that all of these compounds are useful for the same purpose, namely treating herpes simplex virus infection, for example as disclosed by Wright et al., Gilbert et al., or Naesens et al., one of ordinary skill in the art would not have combined 2-phenylamino-9-(4-hvdroxybutyl)-6-oxopurine, which is known to be a thymidine kinase inhibitor, with acyclovir or ganciclovir, which are known to require thymidine kinase activity to be activated *in vivo*. Furthermore, the specification on pp. 13-16 discloses experimental results showing an unexpected synergistic effect when 2-phenylamino-9-(4-hvdroxybutyl)-6-oxopurine (HBPG) is coadministered with foscarnet, cidofovir, or

acyclovir. Thus Applicant has demonstrated unexpected results persuasive to remove the *prima facie* finding of obviousness against these combinations. Therefore the claims meet the requirements of 35 USC 102 and 103.

Accordingly, Applicant's amendment and arguments submitted October 6, 2009, and the enclosed examiner's amendment, are sufficient to remove all rejections made in the prior office action as discussed above and to place the application in condition for allowance.

Any comments considered necessary by Applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled, "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. Olson whose telephone number is 571-272-9051. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric S Olson/
Examiner, Art Unit 1623
12/16/2009

/Shaojia Anna Jiang/
Supervisory Patent Examiner, Art Unit 1623